K030650

UriDynamics Inc.
6786 Hawthorne Park Drive
Indianapolis, IN 46220

Helping You Take Care of Yourself

APR 14 2003

510(k) Summary

Submitted by:
UriDynamics, Inc., 6786 Hawthorne Park Drive, Indianapolis, IN. 46220
Phone/Fax (317) 915-7896
Contact Person: Myron Rapkin
Date Prepared: 2/19/03
Device Name:
Common Name: Visual Reagent Test Strip for Urine pH & Specific Gravity
Trade Name: StoneGuard™ II
Predicate Devices:
pH: Corning Model 313 pH Meter with 3-in-1 Combination Gel-Filled Electrode (Corning)
Specific gravity: *eclipse* Handheld Refractometer (Bellingham & Stanley)
Description:
UriDynamics StoneGuard™ II Test Strips consist of plastic carriers with two reagent pads attached. The pads respond to pH and specific gravity. StoneGuard™ II Test Strips are stored in an opaque vial with desiccant and are ready to use. Results may be read between 30 and 60 seconds after wetting with a freshly-voided urine sample. Results are obtained by comparing the color developed on the pads with a printed color chart. The results are semi-quantitative. Control solutions, Confirm Low™ and Confirm High™, intended for use with StoneGuard™ II Test Strips, are also included in this submission. Confirm Low™ and Confirm High™ contain buffers and salts that give a known response with StoneGuard™ II Test Strips. Confirm Low™ and Confirm High™ Control Solutions are ready to use in dispensers, and contain no biological ingredients.
Intended Use:
StoneGuard™ II Test Strips are for the semi-quantitative estimation of urine pH and specific gravity. StoneGuard™ II Test Strips are intended for use by consumers to monitor urine pH and specific gravity in freshly-voided urine samples to aid in the prevention of kidney stone formation. Readings are made by visual comparison with a color chart.
Confirm Low™ and Confirm High™ Control Solutions are provided to monitor performance of the test strips and to provide quality control for the users.
Substantial Equivalence:
The rationale for substantial equivalence was a comparison between results obtained by untrained participants and reference results obtained by refractometer for specific gravity and pH meter for pH.
Laboratory Studies
Medication Studies: These data demonstrate that commonly-used analgesics and nutritional supplements do not affect the reading of StoneGuard™ II Test Strips.

Blood Interference Studies: Even at the highest levels tested, there was no change in the appearance of the reacted test strips. The presence of blood in urine did not affect the user's ability to interpret the color blocks correctly.

Sensitivity of the Specific Gravity Test: The sensitivity of the specific gravity test was less than one-half color.

Qualification of pH 7.5 Color Block: Color space measurements demonstrate good resolution of pH in the clinically sensitive range of 6.5 to 8.0.

Qualification of 30-60 Second Read Time: Color space readings and timed demonstrated that there was no significant change in readings done between 30 and 60 seconds

Effect of Illumination Type on Test Results: Results demonstrate that results with StoneGuard™ II Test Strips are not affected significantly by changes in illumination.

Accuracy of StoneGuard™ II Test Strip pH & Specific Gravity: At every specific gravity, at least 75% of results were within one-half color block of the expected value. At every pH value, 100% of results were within one-half color block of the expected value. At least 70% of all results agreed with the expected value.

Precision of StoneGuard™ II Test Strip pH & Specific Gravity: At every specific gravity, 100% of results agreed with the expected values. At every pH value, 95% of results agreed with the expected value.

Clinical Studies

Participants: A total of 107 participants were recruited for the study at four sites in Indiana.

Readability Study: With the exception of unavoidable technical language, the package inserts fall within the recommended ranges. The critical, basic directions portion exceeds the recommendation.

Correlation of Consumer & Reference Results: For specific gravity, 92.5% of participant results were within ±0.010 of the reference. For pH, 92.5% of participant results were within ± one-half pH unit of the reference value.

Precision of Repeated Reading: For each test pad, 21 of 22 participants gave identical readings for all four replicate readings.

Precision & Accuracy Using Confirm™ Solutions: Results demonstrate excellent accuracy and precision of the results with Confirm™ Control Solutions.

Survey Response Summary: Most participants found the directions easy to understand and found the test easy to perform. Furthermore, the majority of participants found it easy to match the developed color to the color chart.

pH Interference in the Specific Gravity Test: Analysis demonstrated that specific gravity for StoneGuard™ II Test Strips is low by almost one color block at urine pH 7.5. This is within the effect known for pH error.

Discussion and Conclusions

StoneGuard™ II Test Strips constitutes a robust device for home monitoring of urine pH and specific gravity. Consumer convenience features include:

- 30-second read window
- Confirm Low ™ and Confirm High™ Control Solutions with a wide range of known values
- No significant color change under different types of illumination
- No interference from common medications and nutritional supplements
- No interference from blood, even at high levels

Based on the results of laboratory and clinical studies, we conclude that StoneGuard™ II Test Strips are substantially equivalent to the legally marketed DiaScreen Reagent Strips for Urinalysis (K961374 &K 971976) as well as the Bellingham & Stanley eclipse Handheld Refractometer for specific gravity and the Corning Model 313 pH Meter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 4 2003

Mr. Myron Rapkin
President
UriDynamics, Inc.
6786 Hawthorn Park Drive
Indianapolis, IN 46220

Re: k030650
Trade/Device Name: StoneGuard™ II Test Strips
Regulation Number: 21 CFR 862.1550
Regulation Name: Urinary pH (nonquantitative) test system
Regulatory Class: Class I
Product Code: CEN; JRE; JJW
Dated: February 19, 2003
Received: February 28, 2003

Dear Mr. Rapkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

1.4 Indications for Use

February 19, 2003

Premarket Notification (510(k)) Number: K030650

DEVICE NAME: StoneGuard™ II Test Strips

INDICATIONS FOR USE

UriDynamics StoneGuard™ II Test Strips are intended for semiquantitative measurement of pH and specific gravity in fresh urine. They can be used to monitor conditions that may cause the formation of kidney stones, namely trends in urinary pH and hydration status.

Confirm Low™ and Confirm High™ Control Solutions are intended for in vitro (external) use only, for use as control materials for StoneGuard™ II Test Strips only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Over-the-Counter Use ✓ Prescription Use _____

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030650